Exactech

2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

Exactech®, Inc.
Optecure™ + CCC
Traditional 510(k)

SEP 12 2006

K061668

Traditional 510(k) Summary of Safety and Effectiveness

This 510(k) Summary for Optecure™ + CCC is provided as required per Section 513(1)(3) of the Food, Drug and Cosmetic Act.

Sponsor:

Exactech Inc.
2320 NW 66th Court
Gainesville, Florida 32653
Telephone 352-377-1140
Fax 352-378-2617

FDA Establishment Number 1038671

Contact:

Maritza Elias
Regulatory Representative
Exactech Inc.
2320 NW 66th Court
Gainesville, Florida
Telephone 352-377-1140
Fax 352-378-2617

Proprietary Name: Optecure™ + CCC
Common Name: Bone void filler,
Product Code: MQV, MBP
Device Class: Class II
Classification Name: 21CFR §888.3045 Resorbable calcium salt bone void filler device
Classification Panel: Orthopedic

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Legally Marketed Devices for Substantial Equivalence Comparison:

Product Code	Manufacturer	510(k) Number	Product
MQV, MBP	Exactech Inc.	K050806	Optecure™
MQV	Regeneration Technologies	K043421	Opteform®
MQV, MBP	Osteotech	K051195	Grafton® DBM
MQV, MBP	IsoTis	K050642	OrthoBlast® II
MQV, MBP	Muskuloskeletal Tissue Foundation	K040262	DBX® Demineralized Bone Matrix Mix

Optecure™ + CCC is substantially equivalent to one or more of the 510(k) cleared predicate devices summarized in the above table in that they share similar design, material composition and function.

Device Description:

Optecure™ + CCC is packaged in the form of a kit with pre-measured polymer powder, corticocancellous bone chips (CCC), demineralized bone matrix (DBM), pre-measured mixing solution and all the tools necessary to mix the components. After the powder is hydrated, the resultant putty can then be handled and placed in the appropriate bone voids.

Optecure™ + CCC gradually resorbs and is replaced with new bone during the healing process.

Indications:

Optecure™ + CCC is intended for use as a bone graft extender (extremities, spine and pelvis) and as a bone void filler (extremities and pelvis) for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Optecure™ + CCC may be used with rigid fixation systems.

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Safety & Effectiveness Information

a. Osteoinductive Potential

Samples from each lot of donor demineralized bone matrix (DBM) are formulated with the carrier and tested for osteoinductivity in an in-vivo athymic mouse assay. Findings from the animal model are not necessarily predictive of human clinical results.

b. Viral Inactivation Validation

A viral reduction study was conducted by a CLIA certified testing laboratory using four virus models representing RNA, DNA, envelope and non-envelope virus. This study demonstrates the demineralization process used on donor bone contained in Optecure™ + CCC significantly diminishes these model viruses and can reasonably be anticipated to diminish the titers of other viruses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2006

Exactech
% Ms. Maritza Elias
Regulatory Representative
2320 NW 66th Court
Gainesville, FL 32653

Re: K061668
Trade/Device Name: Optecure™ +CCC
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Codes: MBP, MQV
Dated: June 7, 2006
Received: June 14, 2006

Dear Ms. Elias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act);

21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Barbara Bucholo
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

Exactech, Inc.®
Optecure™ + CCC
Traditional 510(k)

Indications For Use

510(k) Number (if known): _____

Indications for Use:

OpteCure + CCC is intended for use as a bone graft extender (extremities, spine and pelvis) and as a bone void filler (extremities and pelvis) for bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

OpteCure may be used with rigid fixation systems.

Prescription Use X **or** **Over the Counter Use** _____

Barbara Buehrmann for

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K061668